K083818

JAN 2 1 2009

510(k) Summary
for
NeuroMetrix UNIVERSAL Electrodes

1 SPONSOR

NeuroMetrix, Inc
62 Fourth Avenue
Waltham, MA 02451

Contact Person	Rainer Maas
Telephone	(781) 890-9989

Date Prepared	December 19, 2008

2. DEVICE NAME

Proprietary Name	UNIVERSAL Electrodes
Common/Usual Name	Pre-gelled surface electrodes with leads and connector
Classification Name	882 1320 GXY Electrode, Cutaneous

3 PREDICATE DEVICES

- NeuroMetrix UNIVERSAL Electrodes (K081871)
- NeuroMetrix Biosensors (K060584)

4 INTENDED USE

The NeuroMetrix UNIVERSAL Electrodes are intended for use with electrodiagnostic equipment for the recording of electrophysiological activity from peripheral nerves and muscles, and for peripheral nerve electrical stimulation UNIVERSAL Electrodes are non-sterile and are for single patient use only

5 DEVICE DESCRIPTION

Surface electrodes are the interface medium between neurodiagnostic equipment and the patient When used for detection, they transduce bioelectric signals into electronic signals for measurement of bioelectrical phenomena in the body, such as peripheral nerve or muscle responses When used in conjunction with stimulation circuitry in neurodiagnostic devices, they provide the interface necessary to stimulate peripheral nerves Surface electrodes are used in the performance of nerve conduction studies (NCS) They are provided non-sterile and are designed and intended to be for single patient use only and are disposable

- UNIVERSAL Multi-Electrode Set A (UE-004)
- UNIVERSAL Multi-Electrode Set B (UE-005)

These individually placed electrodes are not configured for specific nerves, limbs, or clinical applications They may be repositioned on the same patient up to four times Both of the Multi-Electrode Sets include two surface electrodes in a bar configuration for peripheral nerve stimulation, two pairs of recording electrodes for measurement of bioelectrical potentials, and a reference electrode The pair of recording surface electrodes in Multi-Electrode set A (UE-004) are distinct with one arranged as ring electrodes In Multi-Electrode Set B (UE-005), three surface electrodes are used to create two recording pairs by sharing of one of the electrodes All of the surface electrodes in the Multi-Electrode Sets are individually placed by the user The UNIVERSAL Electrodes include an embedded digital thermometer for measurement of skin-surface temperature, and a ruler (as part of the graphics layers) for the measurement of inter-electrode distances that are used for calculating conduction velocities

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The two UNIVERSAL Electrodes that are the subject of this 510(k) Premarket Notification are substantially equivalent to the predicate UNIVERSAL Electrodes (K081871) The proposed and predicate UNIVERSAL Electrodes share the same intended use, clinical applications, and technological characteristics

The materials, manufacturing process, and packaging for the two new UNIVERSAL Electrodes are the same as for NeuroMetrix Biosensors (K060584) and are therefore also substantially equivalent to these devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2009

NeuroMetrix, Inc
% Mr Rainer Maas
62 Fourth Avenue
Waltham, MA 02451

Re K083818
Trade Name UNIVERSAL Electrodes
Regulation Number 21 CFR 882 1320
Regulation Names Cutaneous Electrode
Regulatory Class II
Product Code GXY
Dated December 19, 2008
Received December 22, 2008

Dear Mr Maas

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known)

Device Name **UNIVERSAL Electrodes**

Intended Use

The NeuroMetrix UNIVERSAL Electrodes are intended for use with electrodiagnostic equipment for the recording of electrophysiological activity from peripheral nerves and muscles, and for peripheral nerve electrical stimulation UNIVERSAL Electrodes are non-sterile and are for single patient use only

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subparts D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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FOR M. MELKERSON

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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